

AMENDED IN ASSEMBLY APRIL 14, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 377

Introduced by Assembly Member Solorio

February 14, 2011

An act to amend Sections 4029 and 4033 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 377, as amended, Solorio. Pharmacy.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies, including hospital pharmacies, by the California State Board of Pharmacy, and makes a knowing violation of that law a crime. Existing law prohibits the operation of a pharmacy without a license and a separate license is required for each pharmacy location. Under existing law, a hospital pharmacy, as defined, includes a pharmacy located outside of the hospital in another physical plant. However, as a condition of licensure by the board for these pharmacies, pharmaceutical services may only be provided to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located and those services must be directly related to the services or treatment plan administered in the physical plant. Existing law imposes various requirements on manufacturers, as defined, and states that a manufacturer does not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.

This bill would provide that a hospital pharmacy also includes a pharmacy, licensed by the board, that may be located outside of the hospital in either another physical plant on the same premises or on a separate premises, located within a 100-mile radius of the hospital, that is regulated under a hospital's license, *but would impose limitations on the services provided by a centralized hospital pharmacy*. The bill would eliminate the conditions of licensure by the board that limit the services provided by the pharmacy in the other physical plant, but would require that any unit-dose medication produced by a hospital pharmacy under common ownership be barcoded to be readable at the patient's bedside. The bill would authorize a hospital pharmacy to prepare and store a limited quantity of unit-dose medications in advance of a patient-specific prescription under certain circumstances. The bill would also provide that a "manufacturer" does not mean a pharmacy compounding or repackaging a drug for parenteral therapy or oral therapy in a hospital for delivery to another pharmacy or hospital under common ownership in order to dispense or administer the drug to the patient or patients pursuant to a prescription or order. The bill would require a pharmacy compounding or repackaging a drug pursuant to this provision to notify the board of the location of the compounding or repackaging within a specified period of time. Because a knowing violation of the bill's requirements would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 4029 of the Business and Professions
- 2 Code is amended to read:
- 3 4029. (a) "Hospital pharmacy" means and includes a pharmacy,
- 4 licensed by the board, located within any licensed hospital,
- 5 institution, or establishment that maintains and operates organized
- 6 facilities for the diagnosis, care, and treatment of human illnesses
- 7 to which persons may be admitted for overnight stay and that meets

1 all of the requirements of this chapter and the rules and regulations
2 of the board.

3 (b) A hospital pharmacy also includes a pharmacy, licensed by
4 the board, that may be located outside of the hospital, in either
5 another physical plant on the same premises or on a separate
6 premises, located within a ~~100-mile~~ 100-mile radius of the hospital,
7 that is regulated under a hospital's license. *A centralized hospital*
8 *pharmacy may only provide pharmaceutical services to its own*
9 *patients who are either admitted or registered patients of a hospital*
10 *within the same health care system.* Nothing in this subdivision
11 shall be construed to restrict or expand the services that a hospital
12 pharmacy may provide.

13 (c) Any unit-dose medication produced by a hospital pharmacy
14 under common ownership, as described in Section 4033, shall be
15 barcoded to be readable at the patient's bedside.

16 (d) A hospital pharmacy may prepare and store a limited quantity
17 of unit-dose medications in advance of receipt of a patient-specific
18 prescription in a quantity as is necessary to ensure continuity of
19 care for an identified population of patients of the hospital based
20 on a documented history of prescriptions for that patient population.

21 (e) Nothing in this section shall limit the obligation of a hospital
22 pharmacy, hospital, or pharmacist to comply with all applicable
23 federal and state laws.

24 SEC. 2. Section 4033 of the Business and Professions Code is
25 amended to read:

26 4033. (a) (1) "Manufacturer" means and includes every person
27 who prepares, derives, produces, compounds, or repackages any
28 drug or device except a pharmacy that manufactures on the
29 immediate premises where the drug or device is sold to the ultimate
30 consumer.

31 (2) Notwithstanding paragraph (1), "manufacturer" shall not
32 mean a pharmacy compounding or repackaging a drug for
33 parenteral therapy or oral therapy in a hospital for delivery to
34 another pharmacy or hospital under common ownership for the
35 purpose of dispensing or administering the drug, pursuant to a
36 prescription or order, to the patient or patients named in the
37 prescription or order. A pharmacy compounding or repackaging
38 a drug as described in this paragraph shall notify the board in
39 writing of the location where the compounding or repackaging is
40 being performed within 30 days of initiating the compounding or

1 repackaging. The pharmacy shall report any change in that
2 information to the board in writing within 30 days of the change.

3 (3) Notwithstanding paragraph (1), “manufacturer” shall not
4 mean a pharmacy that, at a patient’s request, repackages a drug
5 previously dispensed to the patient, or to the patient’s agent,
6 pursuant to a prescription.

7 (b) Notwithstanding subdivision (a), as used in Sections 4034,
8 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, “manufacturer”
9 means a person who prepares, derives, manufactures, produces,
10 or repackages a dangerous drug, as defined in Section 4022, device,
11 or cosmetic. Manufacturer also means the holder or holders of a
12 New Drug Application (NDA), an Abbreviated New Drug
13 Application (ANDA), or a Biologics License Application (BLA),
14 provided that such application has been approved; a manufacturer’s
15 third-party logistics provider; a private label distributor (including
16 colicensed partners) for whom the private label distributor’s
17 prescription drugs are originally manufactured and labeled for the
18 distributor and have not been repackaged; or the distributor agent
19 for the manufacturer, contract manufacturer, or private label
20 distributor, whether the establishment is a member of the
21 manufacturer’s affiliated group (regardless of whether the member
22 takes title to the drug) or is a contract distributor site.

23 SEC. 3. No reimbursement is required by this act pursuant to
24 Section 6 of Article XIII B of the California Constitution because
25 the only costs that may be incurred by a local agency or school
26 district will be incurred because this act creates a new crime or
27 infraction, eliminates a crime or infraction, or changes the penalty
28 for a crime or infraction, within the meaning of Section 17556 of
29 the Government Code, or changes the definition of a crime within
30 the meaning of Section 6 of Article XIII B of the California
31 Constitution.